

REMARKS

Claims 1-4, 6-9 and 11-14 are pending in this application. Claims 6-8, 10-11 and 13-14 are cancelled by this Amendment. Previously, applicants have submitted a replacement sheet for the 'reference designator 581' which the Examiner objected to in Fig. 3, along with the Response to Office Action mailed 10/25/2007, for which no notation or indication of receipt has been noted. It is respectfully submitted that a response to this correction (mandated by the Examiner/Office) is appropriate, and such relief is hereby earnestly solicited.

Likewise, applicants' undersigned representative has made numerous attempts to understand the Examiner's position with respect to how systems unrelated to driving viscous material through a system into a patient from a position remote enough to be outside of a radiation field needed for imagery during back surgery are patently preclusive of the same. The Examiner's ongoing requests for *differentiating* structure have been addressed, with no response forthcoming. Since no system exists in the prior art or marketplace (see Petition to Make Special, and Information Disclosure Statement including March 25, 2008, updated search) reconsideration of the outstanding rejections is respectfully requested, as it is believed that the same remains legally and logically appropriate.

CLAIM OBJECTIONS FROM OFFICE ACTION DATED 12/10/2007

As discussed, claim 11 stands cancelled by way of this Amendment and no further issues are believed to be present.

CLAIM REJECTIONS FROM OFFICE ACTION DATED 12/10/2007

35 U.S.C. Section 112 Rejections of Claim 13 and 14, are mooted as the same are cancelled by this Amendment.

1. 35 U.S. C. Section 102 Rejections of Claims 1-4, 6, 9-11 and 12

Claims 1-4, 6, 9-11 and 12 stand rejected over Peeler's U.S. Letters Patent No. 6,575,331, which is a system for remotely delivering medication to a patient. Claim 1 recites:

“an ergonomically designed pistol-grip handle having a trigger pivotally mounted within a housing” which is not present in the Peeler reference.

Claims 2-4 are dependent from claim 1. Since the Peeler reference does not contain an element of the claims, reconsideration and reversal of the rejection is hereby requested.

In order to overcome an anticipation rejection, the Inventor need only demonstrate that the references fail to teach each and every claimed limitation. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987). Accordingly, reversal and allowance of claims 1-4 is hereby earnestly solicited.

2. 35 U.S. C. Section 103 Rejections of claims 7 and 8.

The rejection of claims 7 and 8 is mooted as they are cancelled. However, applicants' undersigned representative wishes to make clear that claims 1-4, in original and as amended, cannot be obvious over any of the Peeler references, Dumella, or anything disclosed in the IDS.

Therefore, nothing in the act shows an ergonomic hand held trigger which can be used to apply viscous material through a tube. Accordingly, reconsideration of any obviousness rejection is requested in that neither is requested in that neither McGough et al (United States Letters Patent No. 5,015,233) nor any Peeler reference works as applicants' device does.

With regard to the use of “hindsight,” or the use of the Inventor's teachings to combine prior art, the courts have universally condemned such specious Combinations, and have upheld the validity of patents or claims of patents in which such hindsight was employed to combine the references. Notable among the decisions relating to the subject matter is the decision of the Supreme Court of the United States in the case of *Diamond Rubber Co. of New York v. Consolidated Rubber Tire Co.*, 220 U.S. 428, 31 S. Ct. 444 (1911). In this case the Supreme Court stated “[m]any things, and the patent law abounds in illustrations, seem obvious after they have been done, and ‘in the light of the

accomplished result,' it is often a matter of wonder how they so long 'eluded the search of the discoverer and set at defiance the speculations of inventive genius....' Knowledge after the event is always easy, and problems once solved present no difficulties, indeed may be represented as never having had any...." *Id.* at 434-35, 31 S. Ct. at 447 (citation omitted). The Supreme Court then upheld the patent under consideration.

In a similar vein, the Court of Customs and Patent Appeals stated in the case of *In re Kamm and Young*, 172 U.S.P.Q. 298 (C.C.P.A. 1972), that the basic mandate inherent in 35 U.S.C. § 103 is that piecemeal reconstruction of prior art patents in the light of Inventor's disclosure shall not be basis for holding of obviousness. Similarly, in the case of *Ex Parte Lange*, 72 U.S.P.Q. 90, 91 (C.C.P.A. 1947), the Court opined, "It seems to us that the Examiner is using appellant's disclosure for the suggestion of the combination since there is no suggestion in any of the patents for their combination in the manner claimed by Inventor." *See also Ex Parte Myerson*, 72 U.S.P.Q. 49 (C.C.P.A. 1946) and *Ex Parte Gary*, 76 U.S.P.Q. 224 (C.C.P.A. 1947).

The C.C.P.A. also condemned impermissible hindsight in *In re Stephens, Wenzel, and Browne*, 145 U.S.P.Q. 656 (C.C.P.A. 1965) and *In re Leonor*, 158 U.S.P.Q. 20 (C.C.P.A. 1968). In *Stephens*, the Court stated that "[r]eferences may not be combined indiscriminately and with guidance from Inventor's disclosure to show that claims are unpatentable." 145 U.S.P.Q. at 657. In *Leonor*, the court dismissed the examiner's rejection of the claims in suit as "hindsight reconstruction of prior art" and disapproved of the board's affirmation of the rejection on the basis that it "violate[d the] intent and spirit of 35 U.S.C. § 103." 158 U.S.P.Q. at 20-21. Moreover, the court opined that the issue is "whether teachings of prior art would, of themselves, and without benefit of [Inventor]'s disclosure, suggest [a process] which would make claimed invention obvious..." *Id.* at 21.

The Court of Appeals for the Federal Circuit has been equally strong in its condemnation of "hindsight" or similar rejections. For example, in *ACS Hospital Systems, Inc. v. Montefiore Hospital*, 221 U.S.P.Q. 929 (Fed. Cir. 1984), the Federal Circuit reversed a holding of invalidity because there was no teaching to combine the references.

Similarly, the Federal Circuit, in *W.L. Gore Associates, Inc. v. Garlock, Inc.*, 220 U.S.P.Q. 303, 313 (Fed. Cir. 1983), referenced the “insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher, and condemned this type of rejection or holding of unpatentability.”

The Examiner’s rejections are improper based, at least, upon hindsight. As the proposed motivation to combine the references is not directed to the claim differences, that is, elements of the claims, the rejection is improper and must be withdrawn.

Furthermore, any combination of references from the art clearly fails to teach or suggest all of the requirements or elements of the claimed invention. According to cases decided by the Federal Circuit within the last year, the Examiner must explain the motivation, suggestion, or teaching as part of the *prima facie* case. If the explanation is omitted, the Examiner’s rejection is based on impermissible hindsight. In *re Kahn*, (Fed. Cir. 04-1616, March 22, 2006).

Moreover, the Federal Circuit elaborated on the motivation, suggestion, or teaching, stating motivates is decided based on “whether a person of ordinary skill in the art, possessed with the understandings and knowledge reflected in the prior art, and motivated by the general problem facing the inventor, would have been led to make the combination recited in the claims.” *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, (Fed. Cir. 06-1088, October 3, 2006).

U.S.C. § 103 requires that the subject matter “as a whole” must be obvious in order for an invention to be found unpatentable. Of course, recognition of the problem is part of the inventor’s subject matter as a whole, and where the recognition of the problem was not present in the cited art, and where the claims define the entire invention, patentability is clearly present.

Where there is no overall recognition of the problem, the rejection necessarily used Inventor's specification as a road map to reconstruct the claimed invention. One very pertinent supporting decision is the U.S. Supreme Court case of *Eibel Process Co. v. Minnesota and Ontario Paper Co.*, 261 U.S. 45 (1923), in which the U.S. Supreme Court stated "it was discovery of the source (of trouble) not before known and the application of the remedy for which Eibel was entitled to be rewarded in his patent." Early decisions of the Court of Customs and Patent Appeals, the forerunner of the Court of Appeals for the Federal Circuit, are to the same effect. In the case of *In re Worrest*, 96 U.S.P.Q. 381 (C.C.P.A. 1953), the court stated "discovery of problem and concept of new improvement for solving it must also be considered along with the actual physical means of achieving solution."

With regard to "broad-brush" statements regarding motivations or certain matters being "well known in the art" or obvious, the Inventor respectfully traverses all such reasons for rejections, which essentially are asserting facts with no prior art support. In fact, Inventor has chosen components which suit the overall design of the Inventor's apparatus that is utilized in executing the novel and claimed structure. With regard to such unsupported assertions, they have been condemned in a recent decision of the Court of Appeals for the Federal Circuit in the case of *In re Zurko*, 258 F.3d 1379 (Fed. Cir. 2001). In this case the Court stated: "With respect to core factual findings in a determination of patentability, however, the Board cannot simply reach conclusions based on its own understanding or experience — or on its assessment of what would be basic knowledge or common sense. Rather, the Board must point to some concrete evidence in the record in support of these findings." It is further noted that these broad-brush assertions in the rejection are in lieu of citing further references, which would make a rejection of the pending claim based on a further combination of these multiple references even less valid or compelling.

Since this is an extraordinary case allowance of claims 1-4 is appropriate, and they cover a device on the market different from the art.

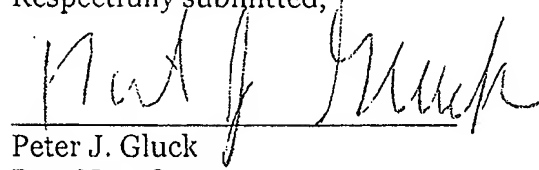
Serial No. 10/776,209

PATENT
Docket No. 079693-010700

Such relief is hereby earnestly solicited, and any fees required may be debited from deposit account number 50,2638.

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Respectfully submitted,

A handwritten signature in dark ink, appearing to read "Peter J. Gluck", is written over a horizontal line.

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APPENDIX A
ORIGINAL CLAIMS - MARKED UP

CLAIM 1 (Original). A pumping system comprising, [in combination:]

a source of fluid for selective pressurization,

a [hydraulic] mechanism for applying [high] pressure to said fluid [
further comprising an ergonomically designed pistol-grip handle having a trigger
pivotally mounted within a housing mounted at upper end of the handle, the housing
including valves mounted therein for controlling the movement of fluid and an
actuator, at a position distal to the trigger on the end of housing allowing manual
pressure release and pressurizing by one hand of a user;]

a conduit for selectively carrying said fluid from said source when said fluid is
pressurized, and a container of a viscous material connected to said conduit to receive
pressurized fluid from said conduit to selectively force said viscous material from said container.

CLAIM 2 (Original). The system recited in claim 1 wherein;

said [the] conduit is a flexible tube.

CLAIM 3 (Original). The system recited in claim 1 wherein;

said source of fluid comprises a reservoir for storing said fluid.

CLAIM 4 (Original). The system recited in claim 1 wherein;

said fluid is an incompressible liquid.

~~**CLAIM 5 (Original).** The system recited in claim 1 wherein;~~

~~—— said container comprises a syringe.~~

~~**CLAIM 6 (Original).** The system recited in claim 1 including, handle means for supporting
said source of fluid.~~

~~**CLAIM 7 (Original).** The system recited in claim 6 wherein;~~

~~—— said mechanism for applying pressure to said fluid comprises, trigger means mounted to
said handle means for selectively applying pressure to said fluid in said source of fluid.~~

~~**CLAIM 8 (Original).** The system recited in claim 6 including, housing means formed with said
handle means,~~

~~—— and valve means mounted in said housing means for controlling the movement of said
fluid from said source of fluid through said conduit.~~

CLAIM 9 (Original). The system recited in claim 1 including, connector means,
for connecting said conduit to said container [wherein the connector means rotates about said conduit to permit selective bleeding of air from said container].

CLAIM 10 (Original). The system recited in claim 9 wherein;
said connector means rotates about said conduit to permit selective bleeding of air from said container.

CLAIM 11 (Original). The system recited in claim 5 wherein;
said syringe includes a plunger movable therein.

CLAIM 12 (Original). The system recited in claim 1 [including], the [a] manual pressure release mechanism operatively connected to said source of fluid for selectively relieving pressure from said fluid [being the actuator located at a portion distal to the trigger on the end of the housing].

~~**CLAIM 13 (Original).** A pumping system comprising,~~
~~a source of fluid for selective pressurization,~~
~~handle means for supporting said source of fluid,~~
~~a mechanism for applying pressure to said fluid,~~
~~said mechanism comprises,~~
~~trigger means mounted to said handle means for selectively applying pressure to said fluid in said source of fluid,~~
~~a conduit for selectively carrying said fluid from said source when said fluid is pressurized,~~
~~and~~
~~a container of a viscous material connected to said conduit to receive pressurized fluid from said conduit to selectively force said viscous material from said container.~~

~~**CLAIM 14 (Original).** The system recited in claim 13 including,~~
~~—— housing means formed with said handle means,~~
~~—— valve means mounted in said housing means for controlling the movement of said fluid from said source of fluid through said conduit, and~~
~~—— connector means for connecting said conduit to said container.~~

~~**CLAIM 15 (Original).** The system recited in claim 10 wherein;~~
~~—— said connector includes,~~
~~—— a hollow housing for receiving an end of said conduit through an axial opening therein,~~

~~— a set screw threadedly engaged with the interior of said hollow housing and surrounding said end of said conduit,~~

~~— seal means surrounding said end of said conduit, and~~

~~— ferrule means surrounding said end of said conduit,~~

~~— said set screw adapted to force said ferrule means and said seal means into contact with the interior of said hollow housing to provide a seal around said conduit in said hollow housing;~~

[Claim 16 (New): The system of claim 1, where the system operates at moderate to high pressures ranging from at least about 1,000 psi to 2,000 psi.]

[Claim 17 (New): The system of claim 1 wherein, said conduit is long enough to permit a user/surgeon to be outside of a radiation field of a patient being imaged.]

[Claim 18 (New): The pumping system of claim 17, further comprising valves within the housing for controlling the movement of said fluid from said source of fluid through said conduit whereby and, a connector which is capable of rotating around the conduit and bleeding off of any air present when the system is operating, both manually and automatically.]

[Claim 19 (New): An improved system for operating a hydraulic pressure pump for medical usage, comprising:

a hand-piece with a housing shaped ergonomically for comfort of a user that provides tactical feedback, having a lever operated hydraulic pump and fluid reservoir;

a connecting tube;

a remote connector which seals to a syringe body;

whereby the pump expels fluid from the fluid reservoir, through the connecting tube into the top of the syringe and where fluid presses on the syringe plunger, thereby expelling the material contained in the primary chamber of the syringe therefrom; and

a low viscosity, inexpensive secondary incompressible fluid is used in the connecting tube lowering the force required to expel material from the syringe, and reducing the volume of injected fluid needed.]

[Claim 20 (New): The improved system for operating a hydraulic pressure pump for medical usage of claim 19, wherein pressures ranging from at least about 1,000 psi to 5,000 psi allow a user to perform procedures in the spine of a patient.]